



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 29 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Grattan C. Woodson, Jr. M.D.  
Woodson and Associates L.L.C.  
P.O. Box 421397  
Atlanta, GA 30342-8397

Re: K981553  
Oasis 4.0 Automated Medical Report Writer  
Dated: August 19, 1998  
Received: August 21, 1998  
Regulatory class: II  
21 CFR 892.1170/Procode: 90 KPS

Dear Dr. Woodson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

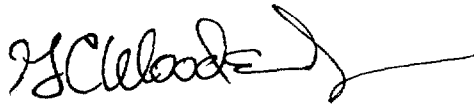
Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

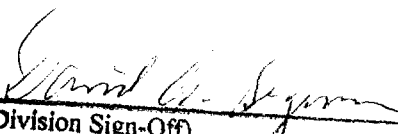
510(k) Number: K981553


Device Name: Oasis 4.0 Automated Medical Report Writer

INDICATIONS FOR USE: Oasis 4.0 is an automated Medical Report Writer intended to be used with the Sahara Bone Sonometer to help communicate the results of the test in a uniform, accurate, and consistent manner. The results are expressed as QUI (Quantitative Ultrasound Index), estimated bone mineral density (BMD), T-score, and Z-score. The estimated BMD is calculated from the QUI. The results are also translated into one of the diagnostic categories – Normal, Osteopenia, or Osteoporosis – based upon the WHO criteria and the normative reference data base. There is standardized language for the estimated risk of fracture and for the therapeutic options which the attending physician may recommend.



Grattan C. Woodson, Jr. M.D.

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K981553

Prescription Use   
(Per 21 CFR 801.109)